

REMARKS

Claims 2-8 and 10-28 are now in the application. The interview so courteously granted by Examiner Haq is hereby noted with appreciation. Claims 2-8, 10-17, 27 and 28 are directed to the elected invention. Claims 18-26 are drawn to non-elected invention and may be cancelled by the Examiner upon the allowance of the claims directed to the elected invention. However, as discussed at the interview, the Examiner will consider rejoicing method claim 18 and claims dependent thereon if the product claims are deemed to be allowable. Claim 2, as discussed at the interview, has been amended to recite that "the magnetic substance being dispersed and encapsulated within the organic polymer material of said particle" and to recite "wherein said organic polymer material comprises a monomer not having a hydrophilic group for forming a core of said particle and a monomer having a hydrophilic group for forming a shell of said particle and forming a particle having dispersion stability in water" for purposes of clarification and not to limit its scope. Basis for the amendments to claim 2 can be found in the paragraph bridging pages 7 and 8 of the specification. Claims 1, 27 and 28 have been amended to recite "comprising" in place of "composing" for purposes of clarification and not to limit their scope. The amendment to the claims does not introduce any new matter.

The rejection of Claims 2-8 and 10-28 under 35 USC 112, second paragraph has been overcome by the above amendment to the claims and/or is not deemed tenable.

Claims 2-8, 10-14 and 27 were rejected as being obvious under 35 USC 103 over US Patent 5,814,687 to Kasai et al. in view of US Patent 5,283,079 to Wang et al. and US Patent 6,773,812 to Chandler et al. The cited references do not render obvious the present invention.

By way of background, an extremely important technical feature of the magnetic substance-encapsulated particle of the present invention is that "the absolute deviation of a component ratio between a carbon element composing the organic polymer material and a metal element composing the magnetic substance is 0.27 or less". This means that the magnetic substance is contained within a particle in a state of being sufficiently dispersed. It is shown that variations in the content of the magnetic substance decrease. In other words, the uniformity of

the magnetic substance-encapsulated particle is enhanced as the value of the deviation decreases. On the other hand, the uniformity of the magnetic substance-encapsulated particle is deteriorated as the value of the deviation increases and variations in the content of the magnetic substance increase. When the absolute deviation of a component ratio between a carbon element composing the organic polymer material and a metal element composing the magnetic substance is 0.27 or less, the reproducibility and the quantitative level of measurement are improved, measuring accuracy becomes better and the reliability of the obtained measurement data is ameliorated when the magnetic substance-encapsulated particle is used in an immunoassay.

Please see Table 6 of the description. The value of "0.27" is the cut off point between Examples according to the present invention and Comparative Examples. The magnetic substance-encapsulated particles of Examples according to the present invention show good performance for immunoassay. However the magnetic substance-encapsulated particles of Comparative Examples show poor performance.

In order to obtain the magnetic substance-encapsulated particles according to the present invention, the specific method disclosed herein is needed. In other words, the value of "0.27 or less" is achieved only when the magnetic substance-encapsulated article are produced by the special method. That is, the method of substance-encapsulated particle comprising the steps of: polymerizing a monomer not having a hydrophilic group and/or a monomer having a hydrophilic group in a water solvent to form a particle; and oxidizing a metal ion while taking in the metal ion into the particle to form a magnetic substance, the step of forming a particle and the step of forming a magnetic substance being simultaneously performed. Most important is "oxidizing a metal ion while taking in the metal ion into the article to form a magnetic substance". In this method, the magnetic substance can be contained within a particle in a state of being adequately and sufficiently dispersed.

Kasai et al, suggest a magnetic polymer particle and process for manufacturing the same. However Kasai's method of producing a magnetic polymer particle that is not capable of producing the magnetic substance-encapsulated particles of the present invention and is quite different from that of present .invention. Please see Example 1 of Kasai et al. The ferritic

superparamagnetic was added to a mixture of monomers. The oily solution containing monomers was added to the waster phase, homogenized, and polymerized. Here, the ferritic superparamagnetic substance is inorganic and the monomers are organic. They are not similar and it is extremely difficult to uniformly mix them. Thus the ferritic superparamagnetic substance can not be contained within a particle in a state of being adequately dispersed as is the present invention. The method suggested in Kasai et al. is merely a common method that is not able to produce the particles of the present invention. Accordingly, Kasai et al. do not enable persons skilled in the art how to make the present invention.

Wang et al. do not overcome the above discussed deficiencies of Kasai et al. with respect to rendering unpatentable the present invention. As pointed out at the interview, Wang et al. suggest a process to make monodispersed fluorescent magnetic particles comprising: coating a fluorescent core polymer particle a magnetically responsive metal oxide and polymer combination, wherein the polymer combination comprises monomers absorb to the inner core polymer particle. This method is not able to produce the particles of the present invention and is also quite different from the present invention. According to Wang, the magnetic particles are present in a coating on the outer surface of the core polymer particles and are not dispersed within the particle as is magnetic material of the present invention. Wang does not even remotely suggest the claimed absolute deviation which is important to the success of the present invention. Moreover, the particle size of the magnetic particles of Wang is orders of magnitude greater than that of the present invention. For instance, please see Example 1, wherein the particle size is 0.8 microns.

Chandler et al. do not overcome the above discussed deficiencies of Kasai et al. and Wang et al. with respect to rendering unpatentable the present invention. Chandler et al. suggest a method of forming magnetically-responsive particles, comprising: associating with a particle at least one magnetic substance in an amount effective for achieving a desired magnetic response. This method is not able to produce the particles of the present invention and is also quite different from that of present invention.

Kasai et al., Wang et al. and Chandler et al. all fail to disclose a range of 0.27 or less for the absolute deviation of a component ratio between a carbon element composing the organic polymer material and a metal element composing the magnetic substance. According to the Office Action, the references disclose use of magnetic particles having uniform size distribution and magnetic content. However the references merely allude to favorable performance of a magnetic polymer particle. They never disclose a range of "0.27 or less" or how to achieve it. The value of "0.27 or less" can not be achieved by the methods described in Kasai et al., Wang et al. and Chandler et al. The cited references fail to enable those skilled in the art how to make the present invention.

Furthermore, the cited art does not specifically refer to absolute deviation and therefore does not recognize it as a result-effective parameter that should be "optimized".

Also, as referred to above, please see Comparative Examples 1-3 and Table 6 of the present specification. The variations in the content of magnetic substance of "Estapor M1-030/40 (produced by Merck & Co., Inc.)" is evaluated. This is a very common for a magnetic substance-encapsulated particles for immunoassay. However the absolute deviation of a component ratio between a carbon element composing the organic polymer material and a metal element composing the magnetic substance exceed "0.27". This is a technical level of the prior art. If the cited documents mention to uniform magnetic content distribution, it must be under the level. They never achieve "0.27 or less". As described above, the method of producing a magnetic substance-encapsulated particle is very important for making the particles of the invention.

Claims 15-17 were rejected as being obvious under 35 USC 103 over US Patent 5,814,687 to Kasai et al. in view of US Patent 5,283,079 to Wang et al. and US Patent 6,773,812 to Chandler et al. and further in view of US Patent 4,568,706 to Noetzel et al. Noetzel et al. do not overcome the above discussed deficiencies of Kasai et al., Wang et al. and Chandler et al. with respect to rendering unpatentable the present invention. Noetzel et al. were relied upon for a disclosure of a cross-linked bead polymer as a carrier of biologically active substance wherein a spacer is used for linking the biologically active substance to the polymer bead. Therefore, claims 15-17 are patentable for at least those reasons as to why claim 2 is patentable.

Claim 28 was rejected as being obvious under 35 USC 103 over US Patent 5,814,687 to Kasai et al. in view of US Patent 5,283,079 to Wang et al. and US Patent 6,773,812 to Chandler et al. and further in view of JP 2003012709 to Ko. Ko does not overcome the above discussed deficiencies of Kasai et al., Wang et al. and Chandler et al. with respect to rendering unpatentable the present invention. Ko was relied upon for a disclosure of microparticles comprising resins from vinylic and acrylic monomers wherein the resins include a monomer that reads on the compound of formula (2). Therefore, claim 28 is patentable for at least those reasons as to why claim 2 is patentable.

In view of the above, consideration and allowance are respectfully solicited.

In the event the Examiner believes another interview might serve in any way to advance the prosecution of this application, the undersigned is available at the telephone number noted below.

The Office is authorized to charge any necessary fees to Deposit Account No. 22-0185, under Order No. 21581-00460-US from which the undersigned is authorized to draw.

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Respectfully submitted,

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